Comments on texts resulting from the Terrestrial Animal Health Code Commission Report – September 2005 Meeting
Submitted by the United States of America

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Suggested change:

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

1. ....

   a) ...

   g) deboned fresh skeletal muscle meat (excluding mechanically separated meat) from cattle ~~30 months of age or less,~~ which were not subjected to a stunning process prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process, and which ~~were subject to~~ passed ante-mortem and post-mortem inspections ~~and were not suspect or confirmed BSE *cases*~~; and which has been prepared in a manner to avoid contamination with tissues listed in Article 2.3.13.13.;

Rationale/Comments:

The United States supports the recommended changes. We would also like to suggest inserting the word "fresh" to more clearly describe the commodity. This insertion would also be consistent with language used in Article 2.3.13.9 through Article 2.3.13.11.

We would also like to recommend the Code Commission expand this list of "fresh meat" products that can be traded regardless of BSE categorization. Please see supporting reference:

Novakofski, J., M/S. Brewer, N. Maeus-Pinilla, J. Killefer, and R. H. McCaskey. Prion biology relevant to bovine spongiform encephalopathy. *J.Anim Sci*. 2005, 83:1455-1476.

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Suggested change:

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that the *commodities* came from:

1. a country, *zone* or *compartment* posing a negligible BSE risk; or

2. a country, *zone* or *compartment* posing a controlled BSE risk; and

   a) skulls and vertebrae (except tail vertebrae) have been excluded if cattle were at the time of slaughter over 30 months of age;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralisation,

      iii) prolonged alkaline treatment, or additional acid treatment,

      iv) filtration,

      v) sterilisation at ≥ 138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Rationale/comments:

Processing used to produce gelatin from bovine bones yields a reduction in infectivity that is sufficient to protect human health. Studies have showed that gelatin is safe for human and animal consumption whether the gelatin is processed by acid demineralization followed by additional acid treatment or by acid demineralization followed by prolonged alkaline treatment.[1]

[1] Grobben, A.H Steele, P.J. Sommerville R.A. and Taylor, D.M. (2004) Biotechnol. Appl. Biochem **39** 329-338.

Not only has scientific research documented the safety equivalency of alkaline processing and acid processing, but also a regulatory precedent has been established in this regard.

Specifically, the European Medical Evaluation Agency (EMEA) has adopted a new revision to their Note for Guidance which either has or will soon be published. In this new Note for Guidance gelatin made by acid processing is deemed equivalent in safety to alkaline processed gelatin.

Accordingly, the United States proposes that Article 2.3.13.14 be changed to reflect this current scientific understanding of bovine bone gelatin processing. The United States requests that Article 2.3.13.14 be clarified and made consistent with Articles 2.3.13.13 and 2.3.13.15 of the *Terrestrial Code*. Specifically, Article 2.3.13.13 delineates that from cattle that were at the time of slaughter over 30 months of age originating from a country, zone or compartment defined in Article 2.3.13.4, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilizers, cosmetics, pharmaceuticals including biologicals, or medical devices: brains, eyes, spinal cord, skull, vertebral column and derived protein products.

Further, Article 2.3.13.15 in point 2, being consistent with Article 2.3.13.13, indicates that tallow and dicalcium phosphate originating from a country, zone or compartment posing a controlled BSE risk and from cattle which have passed ante-mortem and post-mortem inspections, has not been prepared using tissue in points 1 and 2 of Article 2.3.13.13 [which is the material to be removed from all cattle (1) and the material to be removed if the cattle at time of slaughter are over 30 months of age (2)].

Based upon the above rationale, the United States strongly urges that the changes proposed to Article 2.3.13.14 above be made.

Appendix 3.8.4 – Surveillance for Bovine Spongiform Encephalopathy

General Comment: The United States approves and supports the recommended changes to the appendix on BSE surveillance.